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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,118	10/10/2003	Edward G. Walsh	D6477	2749

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/684,118	Applicant(s) WALSH ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *33-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 01/23/2006 is acknowledged.

2. Claims 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/23/2006.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Applicant's claim for the benefit of a prior-filed application 60/417,552 filed 10/10/2002 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged from.

Information Disclosure Statement

5. The information disclosure statement(s) (IDS) submitted on 05/24/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Drawings

6. Examiner notes Figure 4 is intended to be in color. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 21-24, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al (4881526). For claims 1, 3, 27, and 30, Johnson et al discloses an intravaginal muscle diagnosis/treatment device 10 comprising a rigid disposable or non-disposable insertable cylindrical probe 30 with a rounded tip, a plurality of force transducers 94, a plurality of stimulation electrode pairs 16, 18A, 18B, a

plurality of amplifiers 42,100, and a probe position holding means 36 securing said probe within a body lumen.

9. For claims 21-24, Johnson et al discloses disposing single and multiple rows of piezoelectric transducers (column 6 lines 37-40) and electrical stimulation electrodes in a permanently fixed annularly disposed relationship (column 3 lines 5-8).

10. Claims 1-4, 20-24, 26-27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamedi et al (5662699). For claims 1, 3, 26-27, and 30, Hamedi et al discloses an intravaginal muscle diagnosis/treatment device 10 comprising a rigid disposable or non-disposable insertable cylindrical probe 22 with a rounded tip, a plurality of force transducers 32,36, a plurality of stimulation electrode pairs 34,38, a plurality of amplifiers (column 8 lines 8-14) disposed within the nondisposable section, and a probe position holding means 24 securing said probe within a body lumen.

11. For claim 2, Hamedi et al discloses a disposable ribbed sheath 14 inherently capable of measuring insertion depth.

12. For claim 4, Hamedi et al discloses an electrical interface unit 78 comprising amplifiers, generators, parameter control (gain, offset, etc), A-D conversion, and a computer connection means (column 7 line 51 – column 8 line 21).

13. For claims 20-24, Hamedi et al discloses disposing on a sheath single and multiple rows of force measuring transducers and electrical stimulation electrodes in a permanently fixed annularly disposed relationship (column 4 line 64 – column 5 line 65).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 5-6, 15-19, 25, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamedi et al in view of Sarvazyan (5836894). For claims 5-6, Hamedi et al discloses the claimed in vivo measurement probe except for providing battery power to the electrical components and a battery powered portable computer for signal processing. Sarvazyan teaches an in vivo force measurement probe comprising an array of strain gauge pressure sensors 337A, 337B having controlling battery-powered portable electronics including a six channel amplifier 338, an A/D converter 340, a computer 341, and computer connection as seen in Figure 18. It would have been obvious to one having ordinary skill in the art at the time the invention was made

to modify the in vivo measurement probe as taught by Hamedi et al, with Sarvazyan for the purpose of testing/measuring parameters of a patient via a measurement device and portable electronics in a remote and/or comfortable environment.

17. For claims 15-16, Hamedi et al discloses the claimed in vivo measurement/stimulation probe except for the means of holding the probe comprising a probe base connection housing having a probe connector connecting the non-disposable section of the probe within said housing and axial displacement sensors. Sarvazyan teaches an in vivo force measurement/stimulation probe comprising a probe holding means 114 having a connector connecting the non-disposable section of the probe with said housing as seen in Figure 10A and 15A and further comprising axial displacement sensors 103. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in vivo measurement probe as taught by Hamedi et al, with Sarvazyan for the purpose of housing a testing/measuring device that determines the parameters of a patient via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

18. For claim 17, Hamedi et al discloses the claimed in vivo measurement/stimulation probe except for the means of holding the probe comprising a probe base connection housing having a calibrated spring system resisting probe axial displacement . Sarvazyan teaches an in vivo force measurement/stimulation probe comprising a probe holding means 114 having a calibrated spring system 116, 117, 118 resisting probe axial displacement (column 12 lines 59-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in

vivo measurement probe as taught by Hamedi et al, with Sarvazyan for the purpose of housing and calibrating a testing/measuring device that determines the parameters of a patient via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

19. For claim 25, Hamedi et al discloses the claimed in vivo measurement probe except for measuring directional radial force components. Sarvazyan teaches an in vivo force measurement probe comprising an array of strain gauge pressure sensors 337A, 337B for measuring the radial position and orientation of forces (column 2 lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in vivo measurement probe as taught by Hamedi et al, with Sarvazyan for the purpose of testing/measuring parameters of a patient via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

20. For claim 32, Hamedi et al discloses the claimed in vivo pressure measurement probe having stimulation/measurement electrodes that measure electromyography potentials (column 8 lines 8-14) except for simultaneously measuring pressure. Sarvazyan teaches an in vivo force measurement probe comprising an array of strain gauge pressure sensors 337A, 337B for measuring the radial position and orientation of forces (column 2 lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in vivo measurement probe as taught by Hamedi et al, with Sarvazyan for the purpose of testing/measuring

parameters of a patient via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

21. Claims 7-14 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamedi et al in view of Black (6926006). For claims 7-8 and 14, Hamedi et al discloses the claimed in vivo measurement probe except for the probe holding means comprising an examination platform with detachable probe holder that connects to the non-disposable section of the probe. Black teaches a probe holding means comprising table 12 and an adjustable probe holder 76 in detachable engagement with said table and that is adjustable to configure the tilt angle and penetration depth as best seen in Figure 3. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in vivo measurement probe as taught by Hamedi et al, with Black for the purpose of providing a configurable probe holder and platform for the penetration of body orifices by a probe to strengthen pelvic muscles.

22. For claims 9-13, Hamedi et al discloses the claimed in vivo measurement probe except for an examination platform placed on a bed, table or wall-mounted comprising first padded section, second padded section comprising detachable probe holder, handles disposed on first and second sections, and a hinge connecting said first and second sections whereby the platform folds into a parallel relation and is capable of being carried by said handles. Black teaches a an examination platform 10 inherently capable of being placed on a bed or table comprising first padded section 12, second padded section 54 wherein detachable probe holder 76 is adjacently attached, handles

60, 62, 64, 66 disposed on first and second sections, and a hinge 32,34 connecting said first and second sections whereby the platform is inherently capable of folding into a parallel relation and carried by said handles. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in vivo measurement probe as taught by Hamedi et al, with Black for the purpose of providing a configurable probe holder and platform for the penetration of body orifices by a probe to strengthen pelvic muscles.

23. For claims 18 and 19, Hamedi et al discloses the claimed in vivo measurement probe except for a connection housing attachable to probe base connection housing attached to a spring attached to a cross-member and a support structure comprising a padded support structure for an individual's inner thigh. Black teaches a an examination platform 10 comprising a connection housing 76 comprising a leaf spring 72 attached to a cross-member 26 attached to said connection housing and further comprising a support structure 52,56 covered with pads inherently capable of supporting an individual's inner thigh. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the in vivo measurement probe as taught by Hamedi et al, with Black for the purpose of providing a configurable probe holder and padded leg-support structures for the penetration of body orifices by a probe to strengthen pelvic muscles.

24. Claims 28, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. Johnson et al discloses the claimed invention including disposed the electrodes in a proximal relation to the distal tip but does not

disclose expressly the claimed probe diameter and length (column 3 line 55 – column 4 line 12). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify in vivo force measurement and electrical stimulation apparatus as taught by Johnson et al with the claimed dimensions, because Applicant has not disclosed that the dimensions provide an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with intravaginal or intrarectal probe suitable for human anatomy as taught by Johnson et al, because it provides a suitable structure for probing bodily orifices and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Johnson et al.

Therefore, it would have been an obvious matter of design choice to modify Johnson et al to obtain the invention as specified in the claim(s).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH JGH

Max Hindenburg

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